APPENDIX 9 – LABORATORY PROCEDURES FOR PACKAGING AND SHIPPING INFECTIOUS SUBSTANCES AND BIOLOGICAL AGENTS

LABORATORY RESPONSE NETWORK (LRN)

Notice: Protocol subject to change
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Laboratory Procedures for Packaging and Shipping Infectious Substances and Biological Agents (INTERIM)

DISCLAIMER: This document attempts to summarize current regulations (as of 3/10/03) published by the International Air Transport Association (IATA) and the United States Department of Transportation (DOT). In instances where IATA and DOT regulations do not agree, the most conservative (i.e. restrictive) regulation has been used. This document is not all-inclusive and does not contain all information on the subject. IATA and DOT publications are revised frequently. Readers should frequently and regularly consult IATA publications, the Federal Register, and the publications of other governing agencies for more complete instructions. It is the shipper's responsibility to ensure adherence to the most current regulations.

I. Principle and rationale

United States, international, and commercial regulations mandate the proper packaging, documentation, and safe shipment of dangerous goods in order to protect the public, airline workers, couriers, and other persons who work for commercial shippers and who handle the dangerous goods during the many segments of the shipping process. In addition, proper packaging and shipping of dangerous goods will reduce the exposure of the shipper to the risks of criminal and civil liabilities associated with shipping dangerous goods, particularly infectious substances.

The process of properly packaging and shipping an infectious substance or a biological agent is composed of the following sequential steps:

- training of all persons involved in the shipping process (including supervisors)
- determination of the applicability of the regulations
- determination of any applicable shipping limitations
- classification of the substance to be shipped
- identification of the substance to be shipped
- selection of the appropriate packing instructions to use
- selection of appropriate packaging
- marking and labeling the package
- documentation of the shipment

II. Definitions

Biological agents include infectious agents of humans, plants, and animals, as well as the toxins that may be produced by microbes, and genetic material potentially hazardous by itself or when introduced into a suitable vector. Biological agents may exist as purified and concentrated cultures, but may also be present in a variety of materials such as body fluids, tissues, soil samples, etc. Biological agents, and the materials that are known or suspected to contain them, are recognized by federal and state governments as hazardous materials. Their transportation and transfer are subject to regulatory control.

Following are some definitions of terms as they relate to packaging and shipping of Biological Agents:

A. transportation: the packaging and shipping of hazardous materials by air, land, or sea, generally by a commercial conveyance
B. transfer: the process of exchanging hazardous materials between facilities

C. dangerous goods: articles or substances which are capable of posing a risk to health, safety, property or the environment; IATA and DOT have defined nine classes of dangerous goods to be used when items are transported by air:
   1) Class 1: explosives
   2) Class 2: gasses
   3) Class 3: flammable liquids
   4) Class 4: flammable solids
   5) Class 5: oxidizing substances
   6) Class 6: toxic/infectious substances
      Division 6.1 – toxic substances
      Division 6.2 – infectious substances and diagnostic specimens
   7) Class 7: radioactive substances
   8) Class 8: corrosive substances
   9) Class 9: miscellaneous substances (includes dry ice and genetically modified organisms)

D. diagnostic specimen: human or animal material (e.g., tissue, tissue fluid, serum, urine, secreta, excreta, body fluids, blood, and blood components) which is being shipped for diagnostic or investigational purposes, but excluding live infected animals

E. genetically modified microorganism: a microorganism in which genetic material has been purposefully altered in a way which does not occur naturally

F. infectious substance: a material known to contain or reasonably expected to contain a pathogen, including, but not limited to, the following:
   1) pathogens and cultures of pathogens
   2) diagnostic specimens suspected to contain a pathogen
   3) diagnostic specimens from patients with serious disease of unknown etiology

G. complete package: an item properly enclosed in packaging for the purpose of a shipment and ready to be shipped

H. packaging: the materials used to contain a substance and to prepare a substance for shipping, e.g., tubes, containers, boxes, labels, and absorbent material

I. packing: all actions involved in the process of containing, protecting, enclosing, and otherwise preparing a substance for shipment

J. pathogen: a microorganism (including bacteria, viruses, rickettsia, parasites, fungi), recombinant microorganism (hybrid or mutant), or proteinaceous infectious particle (prion) that is known to cause or has the potential to cause disease in humans or animals after exposure

K. shipper: anyone who handles, transports, or offers for transport dangerous goods, or causes dangerous goods to be transported; anyone who completes and signs a *Shippers Declaration for Dangerous Goods*

You, as the shipper - not the transport company - are responsible for the shipment until the package reaches the consignee.

L. risk group: one of four categories (1 through 4) into which infectious substances must be assigned for shipping purposes and which are defined by the ability of the likely microorganism in the substance to cause disease (Table 1). Table 1 contains examples of biological organisms and their associated Risk Groups.

Assignment is based on characteristics of the likely microorganism: pathogenicity, ease and mode of transmission, individual and community risk, and availability of effective treatment for the disease it can cause. Assignment of a substance to a Risk Group is done to help assure subsequent selection of the most appropriate packing instruction to use (602, 650, 904, or 913) to ship the substance.

Table 1. Risk Groups of infectious substances utilized by the LRN

Risk Group	Risk to Individuals	Risk to Community	Examples
4	high	high	smallpox virus
3	high	low	*Brucella* spp., *Bulkholderia mallei, Coxiella burnetii, Francisella tularensis, Yersinia pestis, Venezuelan equine encephalomyelitis virus*
2	moderate	low	Vaccinia virus, *Bacillus anthracis,* most *Enterobacteriaceae*, typical clinical microbiology bacteria
1	none or very low	none or very low	*B. cereus*, normal flora

NOTE: Information obtained from 1998 American Biological Safety Association Risk Group Classification. For a complete listing of risk groups (bacteria, viruses and fungi), see **http://www.absa.org/**. This information is for the United States only (NIH r-DNA-97). Other countries may classify organisms into different risk groups.

Risk group 1 substances are excepted from all Hazardous Materials Regulations unless they meet the definition of another hazard class. Other exceptions include:

- A diagnostic specimen in which the pathogen has been neutralized or inactivated so it cannot cause disease when exposure to it occurs
- A diagnostic specimen or biological product when transported by a private or contract carrier in a motor vehicle used exclusively to transport diagnostic specimens or biological products (check local/state DOT regulations)
- Blood collected for the purpose of blood transfusion or the preparation of blood products and sent for testing as part of the collection process

III. Classification

Classification is a multi-step process to define shipped substances and materials

1) Dangerous goods and infectious substances must be classified as one of the nine IATA classes (Class 1 through Class 9) of dangerous goods. For all practical purposes, Class 6 (toxic/infectious substances) and Class 9 (miscellaneous [dry ice] and genetically modified microorganisms) are the only IATA classes of dangerous goods that routinely apply to clinical microbiologists.
2) Substances in Class 6 are further classified into toxic (Division 6.1) or infectious substances (Division 6.2).

IV. Identification

In the IATA Alphabetical List of Dangerous Goods (the Blue Section), only two of the 3,000 proper shipping names apply to all infectious substances: "Infectious Substance, Affecting Humans" or "Infectious Substance, Affecting Animals." The IATA List (see References) provides information for each proper shipping name (Table 2). The information is contained in 14 columns (A through N; Table 2). This information is essential to know in order to complete a *Shipping Declaration* and to determine if the shipment can be transported in passenger or cargo aircraft, or in cargo aircraft only. IATA Special Provision A81 (and DOT special provision A81 and A82) provides a "consumer friendly" exception from the usually strict limitations in the *List*.

Special Provisions (Exceptions):

1) A shipper may ship more than the small limited amount (50 ml) of infectious body fluid listed in the Max Net Quant/Pkg in Passenger or Cargo Aircraft column (column J). The amount is increased to 1000 ml/primary container and no more than 4000 ml/outer shipping container if the substance is a body fluid and does not contain pathogens in Risk Group 4 (IATA A81 and DOT A81)
2) The limited quantities in the Max Net Quant/Pkg in Passenger or Cargo Aircraft (column J) and the Max Net Quant/Pkg in Cargo Aircraft Only (column L) columns do not apply to human or animal body parts, organs, or whole bodies known or suspected to contain infectious substances. Such materials must be packed according to PI 602 "so as to present no hazard to persons or animals during transport." (IATA A81 and DOT A82)
3) Transport in accordance with this Special Provision must be noted on the *Shipper's Declaration for Dangerous Goods*.

Diagnostic specimens are assigned to UN 3373 unless the source patient or animal has or may have a serious human or animal disease that can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatment and preventative measures are not usually available. In such an instance, they must be assigned to UN 2814 (Infectious Substances, affecting humans) or UN 2900 (Infectious Substances, affecting animals). Assignment to UN 2814 or UN 2900 must be based on known medical history of the patient or animal, or professional judgment concerning individual circumstances of the patient or animal. Blood that has been collected for the purpose of blood transfusion or for the preparation of blood products, and blood products and any tissues or organs intended for use in transplants are not subject to these regulations.

Specimens (human or animal material) known or suspected of containing pathogens meeting the criteria for risk group 2 or 3 may be transported as diagnostic specimens when they are transported for diagnostic or investigational purposes.

Table 2. IATA Alphabetical List of Dangerous Goods

						Passenger or Cargo Aircraft				Cargo Aircraft Only			
						Ltd Quantity							
UN ID Number	Proper Shipping Name/Description	Class	Sub Risk	Hazard Label(s)	PG	Pack Inst	Max Net Wt/Pkg	Pack Inst	Max Net Quant/ Pkg	Pack Inst	Max Net Quant/ Pkg	Spec Prov	ERG Code
A	B	C	D	E	F	G	H	I	J	K	L	M	N
2814	**Infectious substance, affecting humans** *(liquid)	6.2		infectious substance		--	--	602	50 ml	602	4 L	A81[a]	6L
2814	**Infectious substance, affecting humans** *(solid)	6.2		infectious substance		--	--	602	50 gm	602	4 kg	A81[a]	6L
2900	**Infectious substance, affecting animals** * (liquid)	6.2		infectious substance		--	--	02	50 ml	602	4 L	A81[a]	6L
2900	**Infectious substance, affecting animals** *(solid)	6.2		infectious substance		--	--	602	50 gm	602	4 kg	A81[a]	6L
3245	**Genetically modified micro-organisms**	9		miscellaneous		--	--	913	No limit	913	No limit	A47	9L
1845	**Dry ice**	9		miscellaneous	III	--	--	904	200 kg	904	200 kg	A48	9L
3373	**Diagnostic specimen**			none		--	--	650	4 L or 4 kg	650	4 L or 4 kg		6L

* A technical name in parenthesis MUST follow the proper shipping name, e.g., "Infectious substance, affecting humans (hepatitis B virus)".

Key to Columns:

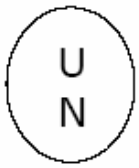
A. the United Nations ID number of the proper shipping name/description
B. proper shipping name/description
C. class of dangerous good
D. N/A
E. the hazardous label required on the outer package
F. N/A
G. N/A
H. N/A
I. packing instructions to use for passenger and cargo aircraft
J. maximum allowable amounts to be shipped in passenger and cargo aircraft
K. packing instructions to use for cargo aircraft only
L. maximum allowable amounts to be shipped in cargo aircraft only
M. applicable special provisions/exceptions
N. emergency response code

N/A - not applicable to infectious goods
[a]DOT special provisions are A81 and A82. For complete equivalent table of US DOT regulations, see http://hazmat.dot.gov

V. Packaging

All packaging must meet UN-specified manufacturing and testing standards for such materials. For all practical purposes, use only commercially available packaging manufactured specifically for shipping dangerous goods.

Commercially available packaging for infectious substances that meets manufacturing specifications is marked in a special and universally recognizable format and style for consumers. A circle containing a "U" over an "N" indicates United Nations specifications have been met. In addition, a series of letters and numbers indicates the type of package, class of goods the package is designed to carry, manufacturing date, authorizing agency, and the manufacturer. An example is given below:



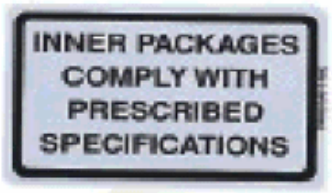
4G/CLASS 6.2/2001
USA/6-20 SHIPPCO

If shippers use commercial packaging, it must be used exactly for its intended purpose and exactly in its tested and certified configuration as documented and advertised by the manufacturer. Packaging and shipping a substance by using materials and components from two manufacturers is dangerous and illegal.

UN (United Nations) SPECIFICATION PACKAGING MUST BE USED FOR ALL SHIPMENTS CONTAINING INFECTIOUS SUBSTANCES AND MAY BE USED FOR DIAGNOSTIC SPECIMENS.

Basic packaging is as follows:

1) Triple Packaging System: For shipping purposes, all infectious substances must be packaged in a three-part container system composed of a primary container, a secondary container, and an outer container. This "triple package" is considered a complete package. The products used in the system must meet the IATA manufacturing standards. Figures 3A and 3B show how these three components can fit together to form a correctly packaged infectious or diagnostic substance. Details regarding packaging requirements can be found in Packing Instructions 602, 650, 904, and 913 (IATA Dangerous Goods Regulations).
2) Overpacks: For convenience and lower costs, one or more complete packages may be shipped in a single box (an "overpack"). Each package in the overpack must be a complete package properly prepared and labeled according to applicable IATA regulations, and the following label must be clearly visible on the overpack: "Inner Packages Comply With Prescribed Specifications".



VI. Packing instructions

NOTE: PRIOR TO SHIPPING ANY SPECIMEN SUSPECTED TO CONTAIN A BIOTERRORISM AGENT, CONTACT YOUR STATE PUBLIC HEALTH LABORATORY FOR SPECIFIC GUIDANCE. ANY MATERIAL THAT MIGHT BE USED AS FORENSIC EVIDENCE IN AN INVESTIGATION MUST BE CONTROLLED BY A CHAIN OF CUSTODY. GUIDANCE FOR THE PROPER USE OF CUSTODY FORMS MAY BE FOUND ON THE LRN WEBSITE.

Shippers are responsible for all aspects of packing infectious substances and must comply with IATA *Packing Instructions* (*PI*). IATA *Packing Instructions* contain specific requirements which, when followed, will assure as much as reasonably possible (1) the safety of persons who handle the packages during shipment, and (2) the arrival of the shipment in good condition at its final destination. The *Packing Instructions* most commonly used in clinical microbiology are those that relate to shipping infectious substances (PI 602), diagnostic specimens (PI 650), dry ice (PI 904), and genetically modified microorganisms (PI 913). The *Packing Instructions* include requirements and information regarding the following:

1) pressure and watertightness specifications of primary and secondary inner packaging
2) physical structure of appropriate outer packaging (containers, boxes, etc.)
3) required markings and labels on outer packaging
4) appropriate use of absorbent material
5) requirements for making advance arrangements with the consignee and the carrier
6) use of wet and dry ice within a shipment

Purified toxin extracted from living sources (e.g., ricin toxin, botulinum toxin) is placed in Division 6.1 and must be labeled as "toxic" with specification number UN 3172 (botulinum) or UN 2810 (ricin toxin). Since multiple packing instructions apply to the shipping of toxins (603, 604, 606, 607, 609, 611, 613, 615, 618, 619, Y609, Y611, Y613, Y619), refer to the IATA Dangerous Goods Regulations to determine the appropriate requirements for the type and quantity of toxin being shipped. Toxins that contain infectious substances or are contained in substances that are infectious should be considered Division 6.2 and assigned to UN 2814 or UN 2900.

A. *PACKING INSTRUCTION 602* (INFECTIOUS SUBSTANCES)

1) Inner Packaging: contains the substance, protects it, prevents it from leaking, and must conform to the testing standards listed in the IATA DGR
   The inner packaging must consist of the following:
   a. a watertight primary container (sift-proof if sample is a solid/powder)
   b. a watertight secondary container
   c. absorbent material placed between the primary and secondary container
      The quantity of absorbent material must be sufficient to absorb all of the fluid contained within all primary containers. Absorbent material is not needed if the substance is a solid. Multiple primary containers shipped within a single secondary container must be individually wrapped to prevent contact between the primary containers. The primary container must be made of glass, metal, or plastic, and must be sealed by a positive method, e.g., heat seal, metal crimp, or taped screw-cap lids.
2) Outer Shipping Packaging: Outer packaging (usually cardboard or paper fib**re**board) is the outermost container, has attached shipping labels and marks, and is likely to receive some degree of abuse during shipping. Outer packaging must conform to the testing standards in the IATA DGR and must exhibit ID number UN 2814 or UN 2900 and UN specification markings.

3) List of Contents: An itemized list of the contents within the primary container(s) must be enclosed in a sealed plastic bag to protect from moisture. This bag must be placed between the secondary container and the outer packaging.
4) Responsible Person: The name and telephone number of the person responsible for the shipment must be written clearly on the outer package.
5) Labels and Markings: Appropriate labels and markings must be affixed to the package to inform carrier of contents (e.g., Infectious substance label, dry ice, etc.). See section VII for examples of labels.
6) Size: Packages must measure $\geq$4 inches in the shortest dimension.
7) Advance Arrangements: Advance arrangements must be made between the shipper, carrier, and consignee to assure arrival of the shipment in good order. In addition, the following statement must be included in the "Additional Handling Information" section of the Shipping Declaration: "Prior arrangements as required by the IATA Dangerous Goods Regulations 1.3.3.1 have been made."
8) Maintenance of a Cold Atmosphere: Wet ice, dry ice, and cold packs must be placed only outside the secondary container. If wet ice is used, its container must be leakproof. DO NOT PLACE DRY ICE INTO A SEALED CONTAINER! IF DRY ICE IS USED, THE OUTER PACKAGING MUST ALLOW THE ESCAPE OF CO_2!
9) *Shipper's Declaration of Dangerous Goods*: required to be completed (typed or electronically generated) and to accompany the completed package
10) For a complete description of requirements, see IATA DGR and DOT HMR.

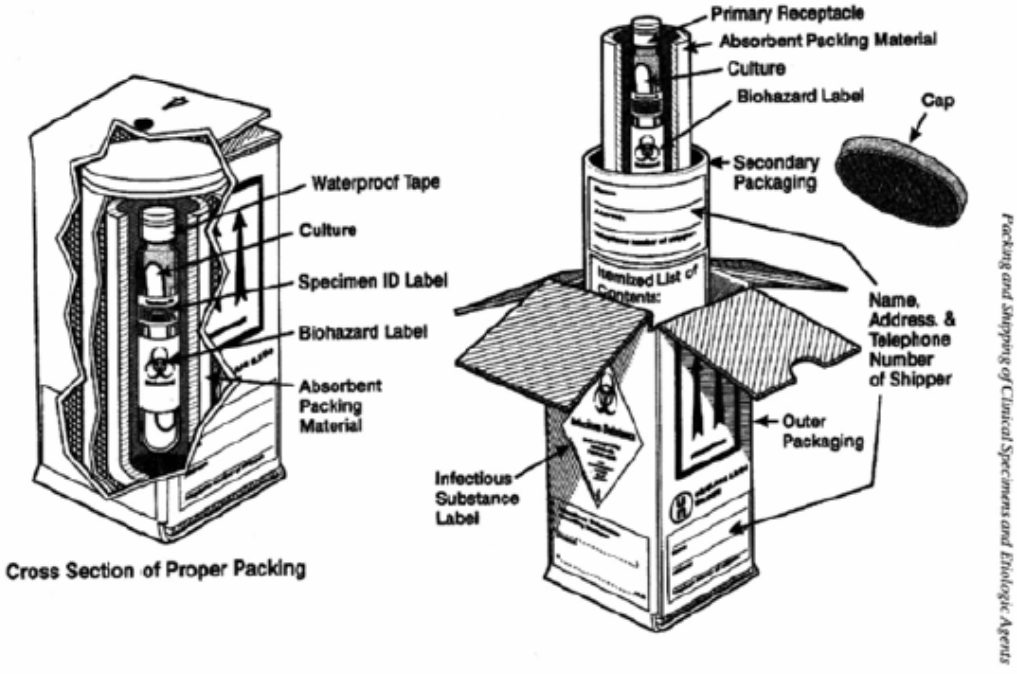


Figure 3A. Example of a correctly prepared and labeled triple package for Infectious Substance (Modified from Biosafety in Microbiological and Biomedical Laboratories [BMBL], 4th edition)

Note: A secondary container does not necessarily have to be a rigid container as suggested by this illustration. The secondary container can be a flexible, tough, envelope-like device which, when inflated and securely closed, is crush-resistant, leakproof and meets all UN specifications and performance tests.

B. *PACKING INSTRUCTION 650* (DIAGNOSTIC SPECIMENS)
   1) Inner Packaging (primary and secondary containers): similar to but not as stringent as PI 602
   2) Outer Packaging: Requirements are less stringent than for PI 602; however, the outer packaging must be adequate in strength for its intended purpose. IATA has assigned UN 3373 to Diagnostic Specimens. US DOT has not assigned a UN ID number to Diagnostic Specimens but it is recommended that the marking be used to ensure compliance with all carriers.
   3) List of Contents: same as PI 602 (NOTE: Place paperwork in a sealed, plastic bag)
   4) Labels and Markings: The following must be on the outside of the completed package: "Diagnostic Specimen Packaged in Compliance with IATA Packing Instruction 650." A preprinted label with this information is commercially available.
   5) Size: same as PI 602
   6) Advance Arrangements: not required
   7) Maintenance of a Cold Atmosphere: same as PI 602
   8) *Shipper's Declaration*: not required
   9) For a complete description of requirements, see IATA DGR and DOT HMR.

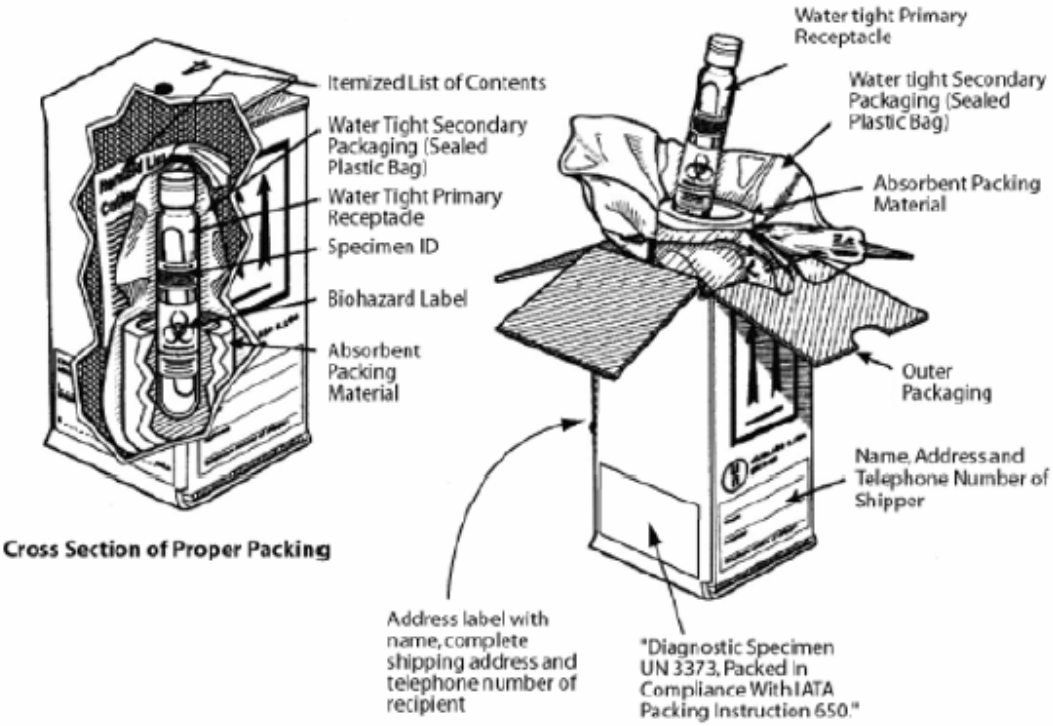


Figure 3B. Example of a correctly prepared and labeled triple package for Diagnostic Substance (Modified from Biosafety in Microbiological and Biomedical Laboratories [BMBL], 4th edition) See note to Figure 3A.

C. PACKING INSTRUCTION 904 (DRY ICE)
1) Outer Packaging: Dry ice must be packaged in a way that allows the escape of CO_2 through the outer packaging and does not allow the build up of pressure.
2) Labeling and Marking: UN 1845 ID number and the net weight (in kg) of the dry ice must be indicated on the outside of the outer packaging. The diamond shaped class 9 label must also be affixed.
3) Advance Arrangements: Advance arrangements must be made between the shipper and the carrier so that the carrier can take appropriate safety precautions.

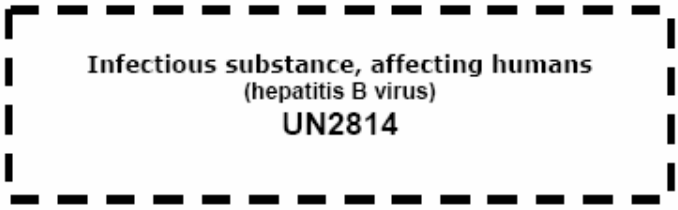
D. PACKING INSTRUCTION 913 (GENETICALLY MODIFIED ORGANISMS)
Genetically modified organisms must be packed according to PI 602 if the shipper considers them to be infectious. For more detailed regulations governing the shipping of genetically modified organisms, see IATA DGR and/or DOT HMR.

Per IATA regulations (2.3.0.1) Dangerous Goods must not be carried by passengers or crew:
as or in checked baggage;
as or in carry-on baggage; or
on their person

VII. Marking and labeling

Marking and labeling an outer shipping container communicates essential information to everyone involved in the shipping process: the contents of the package, the net weight or volume of the material being shipped, the nature of the hazard, and applied packaging standards. Most approved commercially available packaging materials are conveniently pre-printed with the appropriate markings and labels. Additional markings and labels are also commercially available.

1) "Marking" is the act of hand writing or typing on the outer surface of an outer shipping container or overpack and is distinct from "labeling." Each complete package must be clearly marked with the following:
   a. the proper shipping name of the contents and the proper UN ID number (e.g., "Infectious substance, affecting humans [herpes virus] UN2814" or "Diagnostic Specimen UN 3373 packed in compliance with PI 650")



   b. address label
   Include complete name of person, complete facility name, shipping address (street address - no P.O. Boxes) and telephone number (no toll-free numbers: 800-, 888-, etc.) of both shipper and consignee. This information must be on both the outer and inner containers.

c. name and telephone number of a person responsible for the shipment: This person may be the shipper, consignee, or other person as long as the person is trained and certified [see Training section].

Label with "Person Responsible for Shipment"
A 24h/7d telephone number is required (pagers not acceptable)

d. net weight of the dry ice in kg (kg can be calculated by dividing wt in lbs by 2): Weight must be recorded in whole numbers. In calculating amount of dry ice needed, you must consider size of box, volume of material to be kept frozen, and possibility of delays in delivery. The general rule is to use 6 lbs of dry ice per 24 hours of ship time. It is preferable to use excess dry ice than to have the dry ice dissipate prior to arrival. The maximum amount of dry ice allowed to be carried per outer shipping container on a passenger or cargo aircraft is 200 kg.

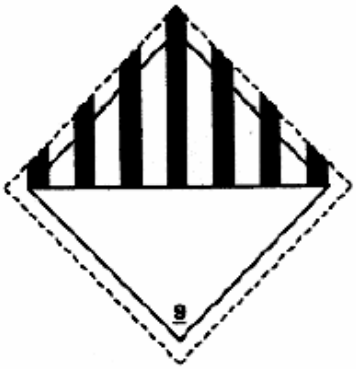
e. indication of Packing Instruction used, e.g., "Diagnostic Specimen Packed in Compliance with IATA Packing Instruction 650" (for diagnostic specimens)

f. net weight of the substance being shipped

2) "Labeling" is the placement of informative, required, and appropriate labels and stickers on the outer surface of an outer shipping container and is distinct from "marking." Labels must be used if the package contains a hazardous substance.

a) Infectious Substance Label: This label is a white diamond with a biohazard symbol and black print which states, "INFECTIOUS SUBSTANCE, In case of Damage or Leakage Immediately Notify Public Health Authority", and a Class 6 number. The label must be at least 100 mm by 100 mm (50 mm by 50 mm for smaller packages).

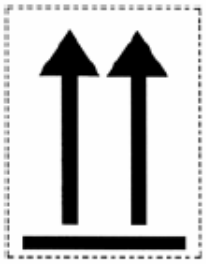
b) Miscellaneous Dangerous Goods Label: This label is a white diamond with black vertical stripes in the upper half of the label and a Class 9 number. The label must be at least 100 mm by 100 mm (50 mm by 50 mm for smaller packages). This label is required when shipping dry ice. Shipment of dry ice also requires a label stating "Carbon dioxide, solid (Dry ice) UN1845 ____kg".



Carbon dioxide, solid
(Dry ice)
UN1845
____kg.

c) Cargo Aircraft Only Label: This label must be placed onto completed packages that can be shipped *only* by cargo aircraft. The label is black on orange, states "Do not Load in Passenger Aircraft," and shows a cartoon character shouting "Danger."

d) Package Orientation Label: Orientation labels are required on the outer shipping container if the contents are ≥50 ml of liquid cultures in primary receptacles of infectious microorganisms. The labels are white with two parallel (either black or red) arrows pointing in the same direction in which the liquid is oriented in the package. A label must be placed onto two opposite sides of the completed package.



A summary of labels and markings required for proper shipping of different types of packages can be found in Figure 5 in the Appendix.

VIII. Documentation

Documentation of shipping infectious substances is accomplished by properly completing a *Shipper's Declaration* (a white document with red diagonal stripes along the left and right edges Figure 3-see appendix). A *Shipper's Declaration* is not required for diagnostic specimens. The *Shipper's Declaration* is completed and signed by the shipper, and is a legal contract between the shipper and the carrier. Carrier and Federal Aviation Administration inspectors have a duty and the right to examine the *Shipper's Declaration* and the contents of package to determine the degree to which the shipper complied with regulations. One copy of the *Shipper's Declaration* is kept by the shipper, and two originals are given to the carrier with the shipment (NOTE: FedEx requires 3 originals). Only the shipper may complete the document. All corrections in a *Shipper's Declaration* must be neatly "lined out" and the change must be signed (not initialed) by the same person who signed the document. Do not use whiteout.
A *Shipper's Declaration* contains the following 20 fields that must be complete and absolutely correct. The numbered fields correspond to those in the sample *Shipper's Declaration* shown in Figures 3 and 4 (see appendix).

1) *Shipper:* the full name and address of the shipper
2) *Consignee*: the full name and address of the consignee, and the name and telephone number of a responsible person in case of an emergency
3) *Air Waybill Number*: can be entered by the carrier or the shipper
4) *Page __ of __:* number of pages of the *Shipper's Declaration* (usually only one)
5) *Aircraft Limitations:* "mark out" the limitation that does not apply
6) *Airport of Departure*: can be entered by the carrier or the shipper
7) *Airport of Destination:* can be entered by the carrier or the shipper
8) *Shipment Type:* "mark out" the type that does not apply
9) *Quantity of Dangerous Goods and Type of Packaging Used*
   These fields are extremely important and must be completed fully and accurately!
   a. *Proper Shipping Name:* proper shipping name and technical name in parenthesis (A comma *must* be placed immediately after the proper shipping name, and parenthesis *must* enclose the technical name! The word "substance" must be singular, not plural. There are NO exceptions!)

*Important note: When shipping BT or Select Agents, on the Shipper's Declaration of Dangerous Goods form under Proper Shipping Name, please use genus spp. instead of specific the genus species name. For example: **do not use "Bacillus anthracis", use "Bacillus spp.".**

b. *Class or Division:* Enter 6.2 if the substance is an infectious substance. Enter 9 for dry ice or genetically modified microorganisms.

c. *UN Identification Number*: The number must be preceded by the prefix "UN". Examples:
UN 2814 Infectious substance, affecting humans (liquid/solid)
UN 2900 Infectious substance, affecting animals (liquid/solid)
UN 3245 Genetically modified microorganisms
UN 1845 Dry ice

d. *Packing Group:* not applicable to infectious substances, for dry ice use packing group III

e. *Subsidiary Risk:* not applicable to infectious substances

f. *Nature and Quantity of Dangerous Goods*
(1) total net quantity of infectious substances
Some carriers require total quantity while others need the quantity broken out. For example, '10 ml' or '2 X 5 ml'. Check with individual carrier for specific requirements.
(2) the number of primary containers (how the substance is divided)
(3) type of material of the outer shipping container
(4) "Overpack Used" if such is the case
Example: 5 ml x 2 (or 10 ml)
All packed in one fib**re**board container (this spelling is required)
Overpak used

g. *Packing Instructions Used:* applicable packing instructions
For example:
PI 602 Infectious Substance
PI 904 Dry Ice
PI 913 Genetically Modified Organisms

h. *Authorization:* Enter any special provisions or exceptions used to bypass usual regulations (e.g., A81 and A82 [see Identification section]).

10) *Additional Handling Information:* At least two required notices regarding special responsibilities must be given in this field:
a. an emergency contact number, including area code: The number *must* be monitored as long as the shipment is in transit [including during incidental storage] and be the number of a person knowledgeable of the substance and who has, or has available, incident mitigation information or has direct access to someone who has such information. Beepers and pagers are not considered "direct access."
b. a statement: "Prior arrangements as required by the IATA Dangerous Goods Regulations 1.3.3.1 have been made."

11) *Name and Title of Signatory*: name and title of person who signs the document (the shipper)

12) *Place and Date:* place and date of signing

13) *Signature:* signature of person who completes the document (the shipper)

IMPORTANT: *Shipper's Declaration for Dangerous Goods* is a legal contract/document, **<u>You must sign this form</u>**

NOTE: Federal Express requires *Shipper's Declarations* to be typed or electronically generated and will not accept handwritten documents. Some carriers may accept handwritten documents. Check with individual carriers to determine their requirements. Federal Express also requires that three (3) originals of the *Shipper's Declaration* accompany the shipment. A *Shipper's Declaration* has many fields, each of which must be completed in an exact way. Entries must be accurate, neat, legible, and correctly spelled and punctuated. Otherwise, the carrier has the right and a duty to reject the shipment. Figure 4 (see appendix) shows a completed and acceptable *Shipper's Declaration*. If *Shipper's Declaration* is not absolutely, positively 100% correct, it is incorrect and will be rejected by the carrier.

A Checklist to help with correct packaging, marking and labeling, and completion of the *Shipper's Declaration* can be found in Figure 6 in the Appendix.

IX. Shipping suspected biological threat agents to the CDC

Label the package as follows:

Centers for Disease Control and Prevention
1600 Clifton Road NE
ATTN: Dr. Richard Meyer, Building 8/9
Atlanta, GA 30333
Office: 404-639-0075, Cell: 404-405-7477

X. Select agents

Select agents are microorganisms, biological agents, or biological toxins that have been deemed by the United States Government to be major threats to public health and safety. Examples of select agents are hemorrhagic fever viruses, *Bacillus anthracis*, *Yersinia pestis*, *Brucella abortus*, *Francisella tularensis*, smallpox virus, *Clostridium botulinum* toxin, and other agents of bioterrorism. See References for a list of Select Agents.

If a known select agent must be shipped or otherwise transported from one facility to another, the shipper must be registered with the Select Agent Program (SAP) at CDC prior to shipment.

XI. Transfers and permits

Regulations on the transfer of biological agents are aimed at ensuring that the change in possession of biological materials is within the best interests of the public and the nation. These regulations require documentation of the personnel, facilities, and justification of need for the biological agent in the transfer process and subsequent approval of the transfer process by a federal authority. The following regulations fit in this category:

A. Importation of Etiologic Agents of Human Disease
42 CFR Part 71 Foreign Quarantine. Part 71.54 Etiologic Agents, Hosts and Vectors. This regulation requires an import permit from the Centers for Disease Control and Prevention for importing etiologic agents of human disease and any materials, including live animals or insects, that may contain them. An application and information on importation permits may be obtained by calling 1-888-CDC-FAXX and enter document number 101000. This information is also available via the Internet at: http://www.cdc.gov/od/ohs/.

B. Importation of Etiologic Agents of Livestock, Poultry and Other Animal Diseases
9 CFR Parts 92, 94, 95 96, 122 and 130. These regulations require an import permit from the United States Department of Agriculture (USDA), Animal and Plant Health

Inspection Service (APHIS), Veterinary Services to import or domestically transfer etiologic agents of livestock, poultry, other animals, and any materials that might contain these etiologic agents. Information may be obtained at (301) 734-3277, or via the Internet at:
http://aphis.usda.gov/vs/ncie.

C. Importation of Plant Pests
7 CFR Part 330. Federal Plant Pest Regulations; General; Plant Pests; Soil; Stone and Quarry Products; Garbage. This regulation requires a permit to import or domestically transfer a plant pest, plant biological agent, or any material that might contain them. Information can be obtained by calling (301) 734-3277 or via the Internet at: http://www.aphis.usda.gov/ppq.

D. Transfer of Select Biological Agents of Human Disease
42 CFR Part 73. Possession, Use, and Transfer of Select Agents and Toxins; Interim Final Rule. Information may be obtained via the Internet at:
http://www.cdc.gov/od/sap/.

E. Export of Etiologic Agents of Humans, Animals, Plants and Related Materials
15 CFR Parts 730 to 799. Department of Commerce. This regulation requires that exporters obtain an export license for a wide variety of etiologic agents of human, plant, and animal diseases (including genetic material) and products which might be used for culture of large amounts of agents. Information may be obtained by calling the DOC Bureau of Export Administration at (202) 482-4811 or via the Internet at: http://bis.fedworld.gov, or http://www.bis.doc.gov.

Failure to Follow Regulations

Failure to follow governmental and commercial regulations for the packaging and shipping of infectious substances can result in criminal prosecution and substantial financial penalties.

XII. Training requirements

The U.S. Department of Transportation (DOT) Hazardous Materials (HazMat) Regulations (HMR), 49 CFR, parts 171-180, as well as IATA DGR, require training for all persons involved in the packaging, shipping, etc. of hazardous materials (including infectious substances). Training can be accomplished by lecture, demonstration, seminars, workshops, self-study, or other means, as long as the goal is met. Private consultants and commercial suppliers of packaging products are good sources of training and training materials. Persons (including supervisors) must be trained if they are considered a shipper, pack at the origination site, pick up for the airline, handle the package as cargo during transport, deliver the goods, etc. Training must consist of the following three components:

A. general familiarization: presentation of governing regulations and provisions
B. function-specific training: detailed instructions of how to perform what the employee-shipper is supposed to do (e.g., package infectious substances, label packages, and prepare documentation)
C. safety training: presentation of the hazards of dangerous goods and emergency procedures

A person is considered trained only when the person's employer creates a written Record of Training that states the person has been trained to the satisfaction of the employer. The Record of Training must contain the following:

1) employee name
2) date of the training
3) a description or copy of the training
4) location of the training
5) name and address of the trainer
6) statement of certification

Training of new employees must be accomplished within 90 days of start of employment or reassignment to shipping duties. Training is valid for two (IATA) or three (DOT) years. Records of training must be kept for two years (IATA) or the duration of employment plus 90 days (DOT).

XIII. Regulating authorities

Several governmental agencies and one major commercial airline trade organization have developed governing regulations for the transportation of dangerous goods (Table 3). The most stringent, comprehensive, widely followed, widely published, and accepted regulations are those written and published annually by IATA which are based on those developed by ICAO. Compliance with IATA regulations usually assures compliance with most, if not all, other regulations. In the United States, the United States Department of Transportation regulates the transportation of dangerous goods. The DOT regulations are found in 49 Code of Federal Regulations (49CFR) parts 100-180. *The information in this document is based predominantly on current IATA and DOT regulations, all of which are subject to interpretation by the shipper.*

Table 3. Agencies governing transportation of dangerous goods

Governing Authority	Agency	Regulations
Commercial airline industry	International Air Transport Association (IATA)	*Dangerous Goods Regulations (DGR)*
United Nations	International Civil Aviation Organization (ICAO)	*The Technical Instructions for the Safe Transport of Dangerous Goods by Air*
United States	Department of Transportation (DOT)	*United States Hazardous Materials Uniform Safety Act* (Code of Federal Regulations 49 [49 CFR])
Canada		*Transportation of Dangerous Goods Regulations* (TDGR)
Other nations		individual regulations

Additional information:
The Centers for Disease Control and Prevention (CDC). 42 CFR Part 73.0. Possession, Use, and Transfer of Select Agents and Toxins. A copy of the current regulation may be obtained via the Internet at: http://www.cdc.gov/od/sap.

Department of Transportation. 49 CFR Parts 171-180. Hazardous Materials Regulations. This regulation applies to the shipment of both biological agents and diagnostic specimens. Information may be obtained from the Internet at: http://hazmat.dot.gov.

United States Postal Service. 39 CFR Part 111. Ability to Mail Etiologic Agents. Codified in the Domestic Mail Manual 124.38: Etiologic Agent Preparations. A copy of the Domestic Mail Manual may be obtained from the Government Printing Office by calling 1-202-512-1800 or via the Internet at: http://www.access.gpo.gov or http://pe.usps.gov.

Occupational Health and Safety Administration (OSHA). 29 CFR Part 1910.1030. Occupational Exposure to Bloodborne Pathogens. This regulation provides minimal packaging and labeling requirements for transport of blood and body fluids within the laboratory and outside of it. Information may be obtained from your local OSHA office or via the Internet: http://osha.gov.

Dangerous Goods Regulations (DGR). International Air Transport Association (IATA). These regulations provide packaging and labeling requirements for infectious substances and materials, as well as diagnostic specimens that have a low probability of containing an infectious substance. These are the regulations followed by the airlines. These regulations are derived from the Committee of Experts on the Transport of Dangerous Goods, United Nations Secretariat, and the Technical Instructions for the Transport of Dangerous Goods by air that is provided by the International Civil Aviation Organization (ICAO). A copy of the DGR may be obtained by calling 1-800-716-6326 or via the Internet at: http://www.iata.org

XIV. References

A. Packaging and shipping infectious substances

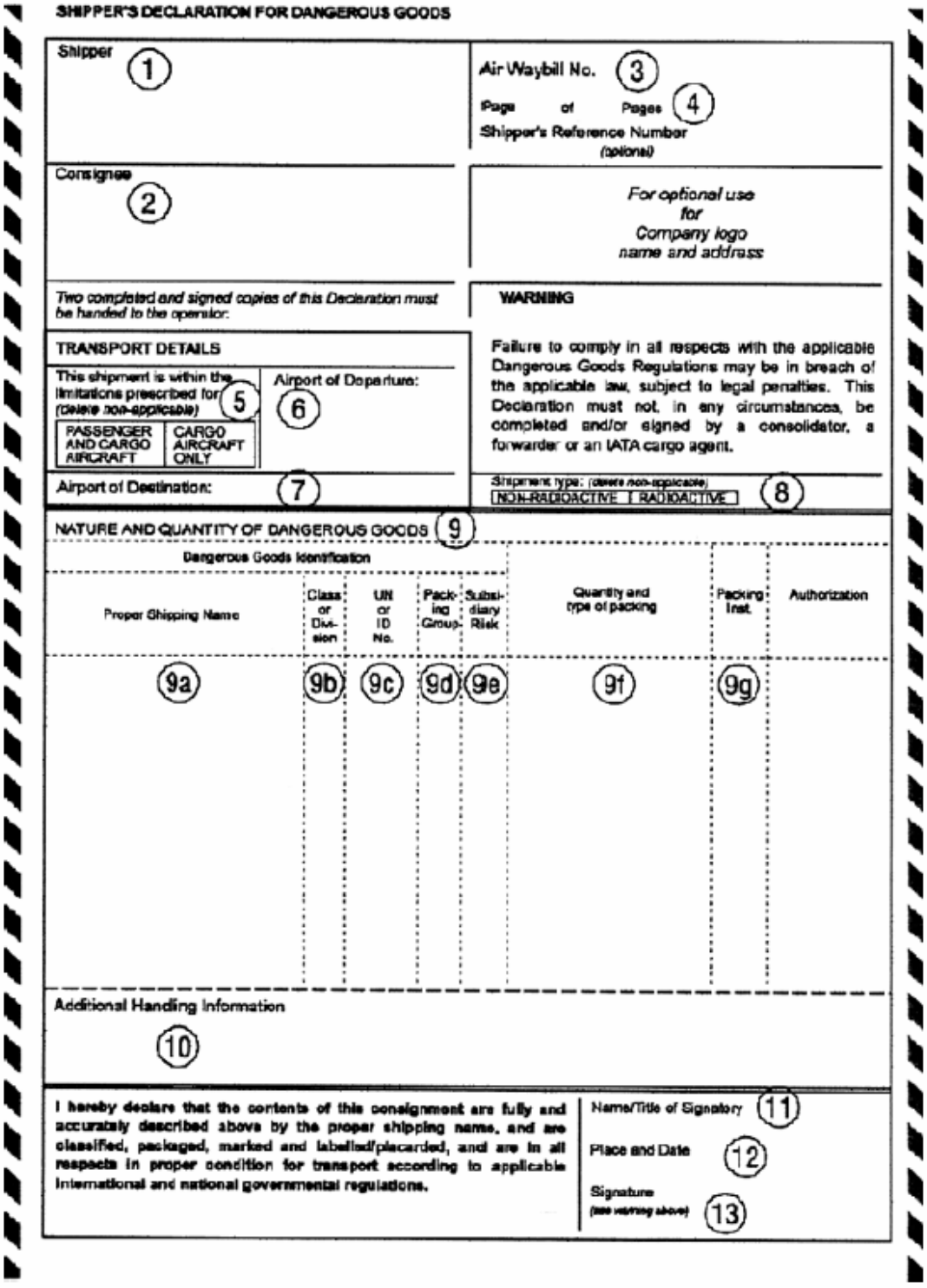
1) Beckala H., 1999. Regulations for packing and shipping laboratory specimens. Lab Med 30:663-667.
2) Centers for Disease Control and Prevention. www.bt.cdc.gov/labissues/PackagingInfo.pdf
3) Department of Transportation. 49 Code of Federal Regulations (CFR) Parts 171-178. August 14, 2002, p. 53118-53144.
4) International Air Transport Association. 2003. Dangerous Goods Regulations. www.iata.org
5) International Air Transport Association. 2002. Infectious Substances Shipping Guidelines. IATA, Montreal, Quebec, Canada.
6) SafTPak, Inc. 2002. 2002 Comprehensive Guide – Shipping Infectious Substances (a training manual). SafTPak, Inc., Edmonton, Canada.
7) Snyder JW. 2002. Packaging and Shipping Infectious Substances. Clin Microbiol Newslet 24:898-93.
8) Biosafety in Microbiological and Biomedical Laboratories, 1999. 4th edition. U. S. Government Printing Office. HHS Publication No. (CDC) 93-8395.
9) American Biological Safety Association. www.absa.org/

B. Select agents

1) Centers for Disease Control and Prevention (www.cdc.gov/od/sap/)
2) American Society for Microbiology (www.asmusa.org/appendixa.htm)

XV. Appendix

Figure 3. Example of a Blank *Shipper's Declaration of Dangerous Goods*



SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper (1)

Air Waybill No. (3)

Page of Pages (4)

Shipper's Reference Number (optional)

Consignee (2)

For optional use for Company logo name and address

Two completed and signed copies of this Declaration must be handed to the operator.

WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.

TRANSPORT DETAILS

This shipment is within the limitations prescribed for: (5) *(delete non-applicable)*

PASSENGER AND CARGO AIRCRAFT | CARGO AIRCRAFT ONLY

Airport of Departure: (6)

Airport of Destination: (7)

Shipment type: *(delete non-applicable)* NON-RADIOACTIVE | RADIOACTIVE (8)

NATURE AND QUANTITY OF DANGEROUS GOODS (9)

Dangerous Goods Identification							
Proper Shipping Name	Class or Division	UN or ID No.	Packing Group	Subsidiary Risk	Quantity and type of packing	Packing Inst.	Authorization
(9a)	(9b)	(9c)	(9d)	(9e)	(9f)	(9g)	

Additional Handling Information (10)

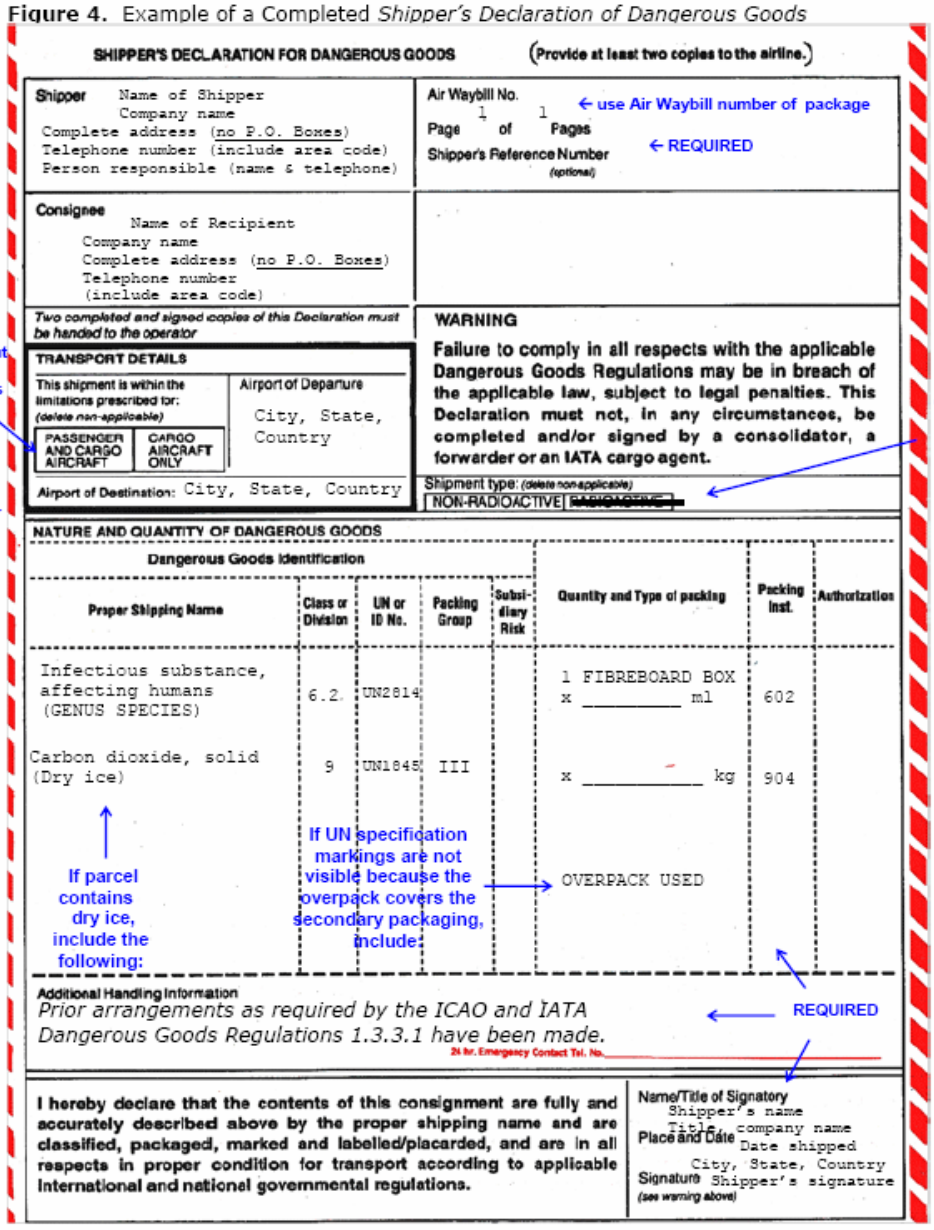
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.

Name/Title of Signatory (11)

Place and Date (12)

Signature *(see warning above)* (13)

Figure 4. Example of a Completed *Shipper's Declaration of Dangerous Goods*



SHIPPER'S DECLARATION FOR DANGEROUS GOODS (Provide at least two copies to the airline.)

Shipper Name of Shipper
Company name
Complete address (no P.O. Boxes)
Telephone number (include area code)
Person responsible (name & telephone)

Air Waybill No. 1 1 ← use Air Waybill number of package
Page 1 of 1 Pages
Shipper's Reference Number (optional) ← REQUIRED

Consignee Name of Recipient
Company name
Complete address (no P.O. Boxes)
Telephone number
(include area code)

← red markings are REQUIRED ←

Two completed and signed copies of this Declaration must be handed to the operator

WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.

Cross-out choice that does NOT apply

TRANSPORT DETAILS

This shipment is within the limitations prescribed for: *(delete non-applicable)*
PASSENGER AND CARGO AIRCRAFT | CARGO AIRCRAFT ONLY

Airport of Departure: City, State, Country

Airport of Destination: City, State, Country

Shipment type: *(delete non-applicable)*
NON-RADIOACTIVE ~~RADIOACTIVE~~

Cross-out choice that does NOT apply

(if quantity >50 ml, transport must occur on cargo aircraft)

(infectious substances are usually non-radioactive)

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification					Quantity and Type of packing	Packing Inst.	Authorization
Proper Shipping Name	Class or Division	UN or ID No.	Packing Group	Subsidiary Risk			
Infectious substance, affecting humans (GENUS SPECIES)	6.2	UN2814			1 FIBREBOARD BOX x _____ ml	602	
Carbon dioxide, solid (Dry ice)	9	UN1845	III		x _____ kg	904	
					OVERPACK USED		

If parcel contains dry ice, include the following:

If UN specification markings are not visible because the overpack covers the secondary packaging, include:

Additional Handling Information

Prior arrangements as required by the ICAO and IATA Dangerous Goods Regulations 1.3.3.1 have been made.

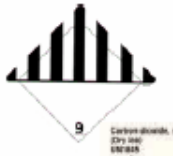
REQUIRED

24 hr. Emergency Contact Tel. No.

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.

Name/Title of Signatory: Shipper's name, Title, company name
Place and Date: Date shipped, City, State, Country
Signature: Shipper's signature *(see warning above)*

Figure 5. Summary of labels and markings required for safe and proper shipping of different types of packages

Package Type:		Inner Packages Comply With Prescribed Specifications				
Diagnostic Specimens	√		√			
Diagnostic Specimens on Dry Ice	√		√	√		
Infectious Substance						
…with less than 50 ml		√ *			√	
…with more than 50 ml	√	√ *			√	√
Infectious Substance on Dry Ice						
…with less than 50 ml		√ *		√	√	
…with more than 50 ml	√	√ *		√	√	√
Dry Ice	√			√		

* *If overpack used*

Figure 6. Checklist

Infectious Substance Packaging Checklist

- ☐ Primary containers - leakproof/watertight
- ☐ Multiple primary containers - separated to prevent breakage
- ☐ Absorbent material - sufficient to absorb entire contents
- ☐ Secondary packaging - UN Specification Packaging for infectious substances (marking visible and not obscured)
- ☐ Itemized list of contents - between secondary container and outer packaging
- ☐ Overpack - if dry ice or cold packs are used

Marking and Labels Checklist

- ☐ Name, facility name, complete shipping address and telephone number of shipper
- ☐ Name, facility name, complete shipping address and telephone number of consignee (recipient)
- ☐ Name and telephone number of person responsible for shipment
- ☐ Class 6.2: Infectious Substance black on white diamond label

- ☐ Class 9: Miscellaneous: Black on white diamond label

(if packed with dry ice)

- ☐ Marking:
  - ➢ UN 2814
    --Infectious substance, affecting humans
    (technical name in parentheses)
    --volume of infectious substance UN 1845
    --Carbon Dioxide, solid (dry ice)
    --weight of dry ice in kg (divide pounds by 2; use whole numbers)
  - ➢ Cargo Only Aircraft black on orange rectangle label if >50 ml/g

- ☐ Mark box "Inner packages comply with prescribed specifications" (If overpack used).
- ☐ Double up arrows black or red on white labels on opposite sides of outer shipper

Checklist

Shipper's Declaration for Dangerous Goods Checklist

3 originals with red/white border stripe
typed or computer generated if shipping
via Federal Express

- ☐ Name, facility name, complete shipping address, and telephone number of shipper
- ☐ Name, facility name, complete shipping address, and telephone number of consignee (recipient)
- ☐ Name and telephone number of person responsible for shipment
- ☐ Air Waybill Number
- ☐ Page ___ of ___
- ☐ Airport of departure (may leave blank)
- ☐ Airport of arrival (may leave blank)
- ☐ Cross out "radioactive" box
- ☐ Cross out aircraft limitation box
- ☐ Proper shipping name -
  --Infectious substance, affecting humans
  (technical name in parentheses)
- ☐ Carbon Dioxide, solid (dry ice)
- ☐ Class or Division – 6; 9
- ☐ UN or ID Number
  UN 2814 (infectious substances)
  UN 2900 (animals)
  UN 1845 (dry ice)
- ☐ Packing Group - III (for dry ice only)
- ☐ Quantity - ml/g; kg
- ☐ Type and number of Packing - Fib**re**board box (note spelling); overpack
- ☐ Packing Instruction – 602; 904
- ☐ 24 hour emergency contact name and number
  (Must supply 24h/7d phone number; no pagers or answering machines)
- ☐ "Prior arrangements made..." statement
- ☐ Name and title of person signing the document
- ☐ Place and date
- ☐ Your signature – required. This is a legal document, contract.
- ☐ Place 2 forms (3 for FedEx) with the other shipping documents.
- ☐ Keep the last form for your records.